**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**THIS DOCUMENT RELATES TO:**<br><br>**ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' NOTICE OF ADOPTION** | **Master File No. 2:12-MD-02327**<br>**MDL 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**MEMORANDUM IN RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE GENERAL OPINION TESTIMONY OF BRIAN MCKINNEY, M.D.**

In Wave 3 of this litigation, Plaintiffs adopt the *Daubert* motions they filed as to the general-causation opinions of Brian McKinney, M.D., in Waves 1 and 2. *See* Pls.' Notice of Adoption (Dkt. 2784). As the Court recalls, Plaintiffs' Wave 1 *Daubert* motion addressed Dr. McKinney's Gynemesh PS opinions, which Plaintiffs have adopted for Wave 3. Plaintiffs also filed a separate Wave 2 *Daubert* motion addressed to Dr. McKinney's separate report for TVT products, which Plaintiffs have also adopted for Wave 3.

The Court has now ruled on the Wave 1 motion. *See generally In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493556 (S.D.W. Va. Aug. 25, 2016). Defendants Ethicon, Inc., Johnson & Johnson, and, where applicable, Ethicon LLC (Ethicon) respectfully request that this Court again deny Plaintiffs' motion for the reasons expressed in Ethicon's Wave 1 and Wave 2 responses (Defs.' Wave 1 Mem. Opp'n (Dkt. 2139); Defs.' Wave 2 Mem. Opp'n (Dkt. 2515)) incorporated here and as supplemented by the reasons set forth below, and in accordance with this Court's August 25, 2016 Memorandum Opinion and Order.

## ARGUMENT AND AUTHORITIES

### I. The Court should reject Plaintiffs' Wave 1 reliability challenges.

#### A. As the Court recognized, Dr. McKinney's testimony based on literature review is sufficiently reliable.

Plaintiffs assert the same argument that that they advanced in Wave 1—*i.e.*, that Dr. McKinney's opinions should be excluded because he failed to take into account medical literature that conflicts with his opinions. This Court rejected that argument, finding Dr. McKinney "explained why he did not rely on or discounted contrary medical literature," so exclusion on medical-literature grounds "is not warranted." *In re: Ethicon, Inc.*, 2016 WL 4493556, at *3. Plaintiffs have not advanced any new argument and, as such, Ethicon respectfully requests that the Court rule in the same manner in the Wave 3 cases and again deny Plaintiffs' motion with respect to their medical-literature challenge.

#### B. Dr. McKinney's opinions are based on medical-literature review *and* his clinical experience, both of which are appropriate methodologies.

Ethicon acknowledges that the Court reserved ruling on the reliability of Dr. McKinney's clinical experience, noting that Dr. McKinney "relies primarily on his experience as the foundation for his opinions." *Id.* As the Court explained, an expert relying primarily on clinical experience, "'must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.'" *Id.* (quoting FED. R. EVID. 702 advisory committee's note to 2000 amendment).

Respectfully, Ethicon has shown in its Wave 1 response that Dr. McKinney's opinions are based not only on his clinical experience, but his extensive review of the medical literature (Defs.' Wave 1 Mem. Opp'n (Dkt. 2139) at 5-7), which, as shown by the Court's August 25 Memorandum Opinion and Order, is a sufficiently reliable basis for his opinions. Even so, Dr. McKinney's clinical experience is vast. As a pioneer in the field of urogynecology, he has

performed thousands of mesh surgical procedures, taught others on proper surgical technique, and has widely published, presented, and conducted research in this area. *See* Ex. B to Pls.' Wave 2 Mot. (Dkt. 2438-3), McKinney TVT Report at 1; Ex. 1 to Defs.' Wave 2 Mem. Opp'n (Dkt. 2515-1), McKinney Prolene Soft Report at 1. This extensive experience is what formed and shaped his opinions that polypropylene mesh products are safe and effective.

> Q. How did you determine that [complications were] rare in your hands? Did you do a retrospective analysis of your cases to see of the cases you have had since going into practice how many of them ultimately went on to develop these serious complications?
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> A. As in an education situation, which I am as a professor, I also have residents and fellows, and we do follow our outcomes, and so, yes.
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> * * *
>
> Q. Can you give us objective evidence of what you're relying upon for your opinion that first the mesh does not shrink?
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> A. Just my personal experience with it that—and from numerous communications and educational talks through—from meetings, but mainly my personal experiences.
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> * * *
>
> Q. So when you talk about your personal experience, is that actually documented somewhere with the use of these very products in abstracts and CME references?
>
> A. Yes.

Ex. E to Pls.' Wave 1 Mot. (Dkt. 2001-5), McKinney 4/14/16 Dep. Tr. 21:22-22:10, 50:23-51:14, 111:4-8; *see also id.* at 12:12-14 ("Since I continue to use polypropylene meshes for reconstruction, I felt that they were safe.").

Ethicon respectfully requests that the Court reject Plaintiffs' clinical-experience argument or, at the very least, reserve ruling in the Wave 3 cases as it did in the Wave 1 cases. *In re: Ethicon, Inc.*, 2016 WL 4493556, at *3.

## II. The Court should reject Plaintiffs' Wave 2 challenges adopted for Wave 3 cases.

### A. Dr. McKinney's opinions are relevant and admissible.

#### 1. Dr. McKinney's opinions regarding native tissue and prolapse repairs are covered by his Rule 26 reports.

Plaintiffs argue that Dr. McKinney's opinions on native tissue prolapse repairs, including his interpretation of the SISTEr clinical trial, are irrelevant because his expert report offers opinions only as to TVT products, which are treatment options for stress urinary incontinence—not prolapse. Pls.' Wave 2 Mem. (Dkt. 2443) at 5-6. Plaintiffs, however, attached to and referenced in their motion only Dr. McKinney's TVT Report. *See* Ex. B to Pls.' Wave 2 Mot. (Dkt. 2438-3), McKinney TVT Report. Plaintiffs failed to consider Dr. McKinney's Prolene Soft Report—which Ethicon submitted in both Wave 1 and Wave 2. *See* Ex. 1 to Defs.' Wave 2 Mem. Opp'n (Dkt. 2515-1), McKinney Prolene Soft Report. Dr. McKinney's Prolene Soft Report covers treatment options for prolapse. *See, e.g., id.* at 19-21. Because Dr. McKinney is opining on both products, his opinions on native tissue prolapse repairs and the SISTEr clinical trial are relevant on that basis.

Further, Plaintiffs seek to preclude Dr. McKinney from testifying about native-tissue repair because native-tissue-repair surgery does not involve synthetic materials. Of course it does not—native tissue repair and TVT implantation are entirely different surgical procedures. But this should be no barrier to Dr. McKinney offering opinions about the advantages and disadvantages of these different surgical procedures—opinions all formed from his decades of surgical experience, counseling patients, and teaching students and practitioners alike. *See, e.g.*, Ex. E to Pls.' Wave 1 Mot. (Dkt. 2001-5), McKinney 4/14/16 Dep. Tr. 103:8-104:18 (emphasizing the importance Dr. McKinney places on educating surgeons about different

surgical procedures and techniques to best limit complications associated with surgery). There is no basis to exclude this testimony.

**2. Even if Dr. McKinney's conclusions regarding the Cochrane Review and Nilsson study make his opinions "inaccurate"—and they do not—that is not a proper basis on which to exclude his testimony.**

Plaintiffs take issue with Dr. McKinney's review and interpretation of the 2015 Cochrane Review and Nilsson study, and the conclusions he reached based upon that review. They argue that Dr. McKinney's conclusions are inaccurate and irrelevant, and therefore that they should be excluded. Pls.' Wave 2 Mem. (Dkt. 2443) at 6-9.

These challenges simply are not part of a proper *Daubert* analysis. Indeed, an expert's interpretation of a study is a matter for cross-examination, not exclusion. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 552 (S.D.W. Va. 2014) ("As the gatekeeper of expert testimony, [the Court] need not concern [it]self with the 'correctness of the expert's conclusions' and should instead focus on the 'soundness of his methodology.'" (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995))). Indeed, even if the medical literature is "not seamlessly align[ed]" with an expert's interpretation of a study or if his interpretation is "subject to debate,"[1] his methodology is not rendered unreliable as long as his interpretation is plausible. *Hovey v. Cook Inc.*, No. 2:13-cv-18900, 2015 WL 1405565, at *5 (S.D.W. Va. Mar. 26, 2015); *see also United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) ("The court need not determine that the proffered expert testimony is irrefutable or certainly correct.").

[1] While Dr. McKinney's opinions are obviously subject to debate, as evidenced by Plaintiffs' motion in the first instance (Pls.' Wave 2 Mem. (Dkt. 2443) at 6-9), challenges to an expert's conclusions are not a proper basis for exclusion; instead, they should be challenged during cross-examination (*Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 678 (S.D.W. Va. 2014); *Tyree*, 54 F. Supp. 3d at 532).

Plaintiffs also claim that Dr. McKinney should be precluded from offering any opinions based on the Nilsson study because his deposition testimony "undermines" his conclusion. Pls.' Wave 2 Mem. (Dkt. 2443) at 8. They then excerpt the purported "undermining" testimony in an attempt to attack Dr. McKinney's conclusions. *Id*. Whatever they were trying to show with this testimony, "undermining" it is not. But even so, any discrepancy between an expert's report and testimony in deposition is a matter for cross-examination, not a basis for exclusion. *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 678 (S.D.W. Va. 2014).

Plaintiffs' attempt to color this as a challenge to Dr. McKinney's methodology—*i.e.*, that these studies do not support his opinions—falls flat. Indeed, as this Court recognized, an expert's methodology is not rendered unreliable just because it is based on studies comparing or discussing other mesh products. *See In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582206, at *2-3 (S.D.W. Va. Sept. 1, 2016) (denying motion to exclude testimony of Dr. Moore based on studies involving different mesh products); *Flandro v. Boston Scientific Corp.*, No. 2:13-cv-17027, 2016 WL 3282734, at *14 (S.D.W. Va. June 14, 2016) (denying challenge to exclude opinions "based on *other* mesh products" (emphasis added)). Because the Cochrane Review and Nilsson study analyze ways to treat the conditions alleged in this litigation, they naturally provide a reliable basis on which Dr. McKinney can ground his safety and efficacy opinions regardless of their discussion of other products.

At bottom, Plaintiffs are challenging Dr. McKinney's conclusions, not his methodology. As *Daubert* and this Court have made clear, challenging the accuracy of an expert's conclusions is not a proper basis for exclusion under *Daubert*; rather, these challenges "are better suited for cross-examination." *Tyree*, 54 F. Supp. 3d at 532; *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *21 (S.D.W. Va. Feb. 7, 2015) ("The plaintiffs, instead, focus their

arguments on why Dr. Clark's ultimate conclusion—that degradation does not occur—is wrong according to other sources. However, under *Daubert*, the court is not to decide whether an opinion is scientifically correct; it is to evaluate the method a proffered expert uses in reaching that opinion."). Because Plaintiffs' challenges here go only to Dr. McKinney's conclusions—not his methodology—their arguments fall outside the scope of a *Daubert* analysis and should be rejected.

**3. Isolated statements taken out of context do not make those statements inadmissible.**

Plaintiffs claim Dr. McKinney's "lowest level of evidence," "Gold Standard," and "escape from the dark ages" statements that are contained in his report are unsupported, prejudicial, and should be excluded. *See* Pls.' Wave 2 Mem. (Dkt. 2443) at 9-10. Plaintiffs selectively quote short phrases from Dr. McKinney's report and call for wholesale exclusion of his opinions related to these phrases. Without more, however, this is no basis for exclusion. Until used in context or otherwise explained, it would be premature to wholesale exclude these statements. As this Court recently noted, a party's use of "out-of-context statements," among other practices, "creates the perfect storm of obfuscation" that compelled this Court to "reserv[e] ruling until the reliability of an expert's testimonial opinion may be evaluated at trial." *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *1 (S.D.W. Va. May 19, 2016).

But even if otherwise, Plaintiffs' "unsupported" argument is baseless. Dr. McKinney sufficiently explains why "case reports and case series" are the lowest level of evidence. Ex. B to Pls.' Wave 2 Mot. (Dkt. 2438-3), McKinney TVT Report at 10. Furthermore, this is not an unsupported opinion in the scientific community. Indeed, case reports merely report an anecdotal individual case uncontrolled for error or bias; a case series is merely a compilation of similarly

uncontrolled case reports. *Tompkins v. Sec'y of Dep't of Health & Human Servs.*, No. 10-261, 2013 WL 3498652, at *24 (Fed. Cl. Ct. June 21, 2013). In the hierarchy of scientific evidence, the scientific community considers these two forms of evidence at the bottom. *Id.*; *see also* FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 724 (3d ed. 2011) (noting that, in determining medical causation, case reports "are at the bottom of the evidence hierarchy," largely because they lack controls); *see also* Ex. B to Pls.' Wave 2 Mot. (Dkt. 2438-3), McKinney TVT Report at 7 ("Case reports and case series are of limited value and do not address the incidence of complications or primary and secondary management."). Moreover, Dr. McKinney's report demonstrates that these opinions are well-reasoned and wholly supported. In his report, he explains:

> The TVT and TVT-O slings have been studied extensively, in over 100 randomized controlled trials (RCTs) and many more other studies, systematic reviews, Cochrane Reviews, metaanalyses, professional society guidelines, analyses, reviews, and position statements. These data are of the highest level of medical and scientific evidence pursuant to the Oxford Levels of Evidence . . . . [citation omitted].
>
> My opinions are based on these high level data and thus my opinions are evidence based, unlike to Plaintiffs' experts who rely on materials which are of the lowest level evidence such as case reports and case series, and in many cases simply irrelevant such as emails, documents, literature and excerpts of testimony concerning hernia mesh and prolapse devices.

Ex. B to Pls.' Wave 2 Mot. (Dkt. 2438-3), McKinney TVT Report at 10.

As for the "Gold Standard" statement, there is nothing unsupported about that statement when viewed in context. He explains the studies that support this statement and opinion, and the multitude of organizations that have studied and endorsed the TVT and TVT-O:

> It is my opinion that the TVT and TVT-O are the gold standard and current standard of care for the treatment of SUI. It is my opinion that the TVT and TVT-O are safe and effective. My opinions are supported by major urologic an urogynecologic surgeon associations and societies.

*Id.* at 25-26 (listing various position statements issued by numerous associations that support Dr. McKinney's "Gold Standard" statement, including the National Institute for Health and Care Excellence, AUA, AUGS, IUGA, among others); *see also id.* at 7-8 (explaining that several organizations have recognized TVT and TVT-O "as the Gold Standard, standard of care, and first line and suitable surgical option to treat stress urinary incontinence"). Thus, Dr. McKinney's "Gold Standard" statement and opinion is fully supported. And, even if it were not, cross-examination—not exclusion—is the proper basis for challenging this opinion. *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 505234, at *3 (S.D.W. Va. Feb. 5, 2014) (denying motion *in limine* to exclude references to TVT being the "gold standard" and noting that "[i]f the plaintiffs believe that terms like 'golds standard' are imprecise and confusing, they may cross examine the witnesses"); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3861778, at *2 (S.D.W. Va. Aug. 6, 2014) (same).

Viewed in context, as the statements contained in Dr. McKinney's report should be, the statements Plaintiffs challenge are adequately supported. It would be improper to take these isolated statements out of the context they were offered and wholly exclude them. Plaintiffs' argument to the contrary should be rejected.

### B. Dr. McKinney's opinions are based on his clinical experience and review of the medical literature—both well-accepted methodologies for formulating expert opinions.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem*, 57 F. Supp. 3d at 714. This Court in particular has made clear that a physician can draw upon his clinical experience

and review of relevant literature to give an opinion on the safety and efficacy of polypropylene mesh products. *See Tyree*, 54 F. Supp. 3d at 585 (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of polypropylene mesh products).

Plaintiffs, however, criticize several of Dr. McKinney's opinions as being infirm because they are unsupported by the medical literature or his experience. First, they claim that Dr. McKinney could not know "frustrations" of surgeons. Pls.' Wave 2 Mem. (Dkt. 2443) at 11. Yet, Dr. McKinney—a pioneer in the field of urogynecology—has been a leader in this field. He has taught hundreds of courses on pelvic reconstruction, and indeed started a company that has taught others on unembalmed cadavers to "to do a more anatomical repair." Ex. B to Pls.' Wave 2 Mot. (Dkt. 2438-3), McKinney TVT Report at 2, 4. He has conducted research, published widely, given numerous presentations, and written chapters in textbooks. *Id*. at 2-3. Given this breadth of experience and discourse with his colleagues related to treatments for both stress urinary incontinence *and* prolapse repair, he is well acquainted with the common frustrations among those in his field pertaining to these treatments.

Second, Plaintiffs take issue with Dr. McKinney's statement that Ethicon's products "represent an escape from the dark[] ages" and that surgery is the "most definitive treatment" for stress urinary incontinency. They claim the former is as prejudicial and misleading while the latter is "vague and ambiguous," and its meaning is unclear. Pls.' Wave 2 Mem. (Dkt. 2443) at 10-11. Certainly taking a statement out of context and in isolation may make any statement's meaning unclear or misleading. Viewed in context, Dr. McKinney is giving background on the various treatments for stress urinary incontinence (of which implanting TVT products is included) and the success rates associated with earlier treatment options:

> Surgery for SUI has been shown to be the most definitive treatment. Surgery for SUI includes the Burch colposuspension, native/biologic tissue slings and most often, synthetic slings. Monofilament, large pore polypropylene like that used in TVT and TVT-[O], is the most common type of synthetic material used in slings.
>
> * * *
>
> Potential risks of SUI surgery are well described to surgeons during training, in medical textbooks, and in the medical literature, and are well known elemental risks that surgeons would be aware of and are in common for most pelvic floor reconstruction. The Bergman study of 1995 demonstrates what we had before TVT/TVT-[O] and had serious shortcoming[s], especially with the standard at the time being the Kelly plication (37% 5 [year] success rate) and Needle suspension slings of the Stamey/Raz variety (42%). It was also pointed out by Zivkovic and later by Benson that the dissections around the urethra lead to 40-65% denervation of the nerves to the sphincter and in doing that lead to Intrinsic Sphincter Deficiency. The minimally invasive Mid Urethral slings have been a tremendous advance and represent an escape from the dark[] ages. I believe with all my educational prowess that TVT/TVT-O is the safest and most effective surgery for [s]tress urinary incontinence with the least risks of complications [versus] all invasive incontinence surgeries.

*See* Ex. B to Pls.' Wave 2 Mot. (Dkt. 2438-3), McKinney TVT Report at 5-6, 10, 32. There is no per se "opinion" attached specifically to these statements other than they give background for the opinions ultimately expressed. As such, there is nothing prejudicial or misleading.

Third, Plaintiffs claim Dr. McKinney's opinion that TVT products have the "longest and broadest track record of safe and effective use" should be excluded because his reliance on the SISTEr clinical trial, Cochrane Review, and Nilsson study is "fundamentally flawed." Pls.' Wave 2 Mem. (Dkt. 2443) at 11. But, as already discussed, Plaintiffs' criticisms go to Dr. McKinney's ultimate conclusions—not his methodology—which is not a proper basis for exclusion. *See supra* Part I.B. Given that he reached this opinion relying on his review of the

literature, which is an acceptable methodology, there is no basis to exclude his safety and efficacy opinions.

And lastly, they argue that Dr. McKinney's pore-size opinion is unsupported, which they claim he essentially conceded in deposition. Pls.' Wave 2 Mem. (Dkt. 2443) at 11-12. Plaintiffs misstate Dr. McKinney's testimony and misunderstand the analysis for admissibility under *Daubert*. The testimony excerpted on page 11 of their memorandum merely shows that Dr. McKinney did not conduct a search of the literature "specific to vaginal mesh pore size." *Id.*; *see also* Ex. D to Pls.' Wave 2 Mot. (Dkt. 2438-5), McKinney 6/29/16 Dep. Tr. 34:22-35:1. It does not show that his pore-size opinions are unsupported. In fact, a complete reading of Dr. McKinney's deposition shows that he based his pore-size opinions on a review of two studies—the Falconer and Ahmed (Amid) studies. Ex. D to Pls.' Wave 2 Mot. (Dkt. 2438-5), McKinney 6/29/16 Dep. Tr. 32:16-34:14; *see also* Ex. B to Pls.' Wave 2 Mot. Dkt. 2438-3), McKinney TVT Report at 21 ("Pore size affects the inflammatory response and resultant connective tissue formation within the mesh structure[. T]hus macroporous meshes promote tissue host ingrowth with macrophages, leukocytes, fibroblasts, blood vessels and collagen to transverse the > 75 um pores. These factors allow for and result in biocompatibility and low risk of infection." (citing P.K. Amid, *Classifications of Biomaterials and Their Related Complications in Abdominal Wall Surgery*, 1 HERNIA 1 (1997)).[2]

Given that these opinions are based on Dr. McKinney's review of relevant medical literature—an accepted scientific methodology—Plaintiffs' challenge should be rejected.

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[2] The Amid study is specific to the same exact material used in TVT and TVT-O: polypropylene mesh. *See* Ex. A, P.K. Amid, *Classifications of Biomaterials and Their Related Complications in Abdominal Wall Surgery*, 1 HERNIA 1 (1997). Because this study is used to support Dr. McKinney's pore-size opinion—*i.e.*, the material aspect of the mesh—it makes no difference that the mesh discusses its use in hernia repairs and not as treatment for SUI.

**C. Dr. McKinney's IFU testimony is admissible.**

Plaintiffs take issue with Dr. McKinney's IFU testimony—elicited by Plaintiffs' counsel—as to Dr. McKinney's general perceptions about what should be included in an IFU and how an IFU is used by physicians in general. *See* Pls.' Wave 2 Mem. (Dkt. 2443) at 14. Plaintiffs frame this argument as an "adequacy" argument, but the testimony Plaintiffs point to in their memorandum says nothing about IFU adequacy. Instead, Dr. McKinney is expressing his opinion, in response to Plaintiffs' counsel's questioning, about the "basic premise" of an IFU in general and how an IFU is used, or should be used, in practice. *Id*. Although "[d]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings" (*Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015)), Dr. McKinney's IFU testimony challenged by Plaintiffs here is not an "adequacy" opinion at all much less an opinion as to whether the IFUs at issue here, in particular, are adequate.

Plaintiffs' reliance on this Court's decision in *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D.W. Va. 2013), does nothing to advance their argument. In that case, the Court addressed an expert's qualifications to provide an opinion about what should have been included in a product's warnings. *Id*. at 611. The opinion testimony excerpted at page 14 of Plaintiffs' memorandum offers no such opinion. *In re C.R. Bard* is wholly irrelevant.

At bottom, Dr. McKinney is well qualified to offer the nonspecific, general testimony about how IFUs are used by physicians in general. As a pioneer in this field, he has performed thousands of mesh surgical procedures, taught others on proper surgical technique, and has widely published, presented, and conducted research in this area. *See* Ex. B to Pls.' Wave 2 Mot. (Dkt. 2438-3), McKinney TVT Report at 1; Ex. 1 to Defs.' Wave 2 Mem. Opp'n (Dkt. 2515-1),

McKinney Prolene Soft Report at 1. In fact, as a practicing surgeon who went through years of medical education and training, has extensive clinical experience with pelvic-floor surgeries, teaches other physicians about these surgeries, and keeps up with the medical literature, Dr. McKinney is uniquely qualified to offer opinions about the "basic premise" of IFUs in general and how physicians in general use and rely on a product's IFU. Indeed, only physician with this training and experience could testify provide this testimony. Plaintiffs' IFU argument should be rejected.

**D. Dr. McKinney will not offer opinions on the 510(k) process.**

Plaintiffs correctly note that Dr. McKinney did not offer opinions concerning the 510(k) clearance process in his Rule 26 report. Plaintiffs nonetheless questioned Dr. McKinney at length about his opinions on this issue at deposition. Ex. D to Pls.' Wave 2 Mot. (Dkt. 2438-5), McKinney 6/29/16 Dep. Tr. 29:18-31:20. Ethicon will not be offering these plaintiff-initiated opinions; thus, Plaintiffs' request for their exclusion is moot.

**CONCLUSION**

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety or limited as set forth above.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on October 10, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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